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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1308**

**[Docket No. DEA-476]**

**Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Temporary amendment; temporary scheduling order.

**SUMMARY:** The Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to schedule fentanyl-related substances that are not currently listed in any schedule of the Controlled Substances Act (CSA) and their isomers, esters, ethers, salts and salts of isomers, esters, and ethers in schedule I. This action is based on a finding by the Administrator that the placement of these synthetic opioids in schedule I is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle fentanyl-related substances.

**DATES:** This temporary scheduling order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], until February 6, 2020. If this order is extended or made permanent, the DEA will publish a document in the *Federal Register*.

**FOR FURTHER INFORMATION CONTACT:** Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

**SUPPLEMENTARY INFORMATION:**

**Legal Authority**

Section 201 of the Controlled Substances Act (CSA), 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance permanently are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Attorney General may extend the temporary scheduling<sup>1</sup> for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355. 21 U.S.C.

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<sup>1</sup> Though DEA has used the term “final order” with respect to temporary scheduling orders in the past, this notification adheres to the statutory language of 21 U.S.C. 811(h), which refers to a “temporary scheduling order.” No substantive change is intended.

811(h)(1). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

## **Background**

### *The Nature of the Problem and DEA's Approach to Correct It*

It is well known that deaths associated with the abuse of substances structurally related to fentanyl<sup>2</sup> in the United States are on the rise and have already reached alarming levels. While a number of factors appear to be contributing to this public health crisis, chief among the causes is the sharp increase in recent years in the availability of illicitly produced, potent substances structurally related to fentanyl. Fentanyl is approximately 100 times more potent than morphine, and the substances structurally related to fentanyl that DEA is temporarily controlling also tend to be potent substances. Typically, these substances are manufactured outside the United States by clandestine manufacturers and then smuggled into the United States.

Fentanyl is often mixed with heroin and other substances (such as cocaine and methamphetamine) or used in counterfeit pharmaceutical prescription drugs. As a consequence, users who buy these substances on the illicit market are often unaware of the specific substance they are actually consuming and the associated risk. According to the Centers for Disease Control and Prevention (CDC), drug overdose deaths involving synthetic opioids (excluding methadone), such as fentanyl and tramadol, increased from 5,544 in 2014 to 9,580 in 2015. According to provisional data released in August 2017

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<sup>2</sup> As explained further below, in this document, the term "fentanyl-related substances" is defined to include substances structurally related to fentanyl but which are not controlled under a separate scheduling action (listed under another Administration Controlled Substance Code Number). Thus, all "fentanyl-related substances" are structurally related to fentanyl, but some fentanyl-related substances are controlled under separate scheduling actions.

by the CDC, National Center for Health Statistics, an estimated 55 Americans are dying *every day* from overdoses of synthetic opioids (excluding methadone).<sup>3</sup> Drug overdose deaths involving synthetic opioids excluding methadone for the 12-month period ending in January of 2017 (20,145 deaths) more than doubled from the corresponding data for the period ending in January of 2016 (9,945 deaths).

DEA has responded to this crisis by issuing eight temporary scheduling orders to control seventeen substances structurally related to fentanyl since 2015. However, this approach has not been completely effective in preventing the emergence of new substances structurally related to fentanyl. This is because when DEA temporarily controls a given substance structurally related to fentanyl, illicit manufacturers located abroad begin producing new such substances through other structural modifications. Those new nonscheduled substances then are smuggled into the United States, where they are distributed by traffickers in this country as a purportedly "noncontrolled" substance.<sup>4</sup> In this way, traffickers are effectively circumventing the temporary control mechanism that Congress established under 21 U.S.C. 811(h) to combat newly emerging dangerous drugs. Post mortem toxicology and medical examiner reports collected by the DEA show mortality connected to substances structurally related to fentanyl. Control of these substances is necessary to avoid an imminent hazard to the public safety.

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<sup>3</sup> Provisional synthetic opioid death overdose counts are based on CDC data available for analysis as of August 6, 2017, based on the 12-month reporting period ending January 2017. See [https://www.cdc.gov/nchs/data/health\\_policy/monthly-drug-overdose-death-estimates.pdf](https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf) accessed 09-06-2017.

<sup>4</sup> Such trafficking is actually illegal as persons who do so can be prosecuted using the controlled substance analogue provisions of the CSA. 21 U.S.C. 802(32), 813. However, prosecution under the analogue provisions requires proof of additional elements not required for prosecuting trafficking in scheduled substances.

Given the gravity of the ongoing fentanyl-related overdose crisis in the United States, protection of the public safety demands the utilization of 21 U.S.C. 811(h) in a manner that cannot be readily circumvented by drug traffickers. Specifically, in issuing this temporary scheduling order, DEA exercises its authority to avoid an imminent hazard to the public safety by placing fentanyl-related substances, as defined later in this document, in schedule I. As explained below, these fentanyl-related substances – including those that have not yet been introduced by traffickers into the U.S. market – present a significant risk to the public health and safety and need to be controlled under section 811(h) to avoid an imminent hazard to the public safety. It should also be noted that none of the substances that is being temporarily controlled has a currently accepted medical use in treatment in the United States; nor is any of the substances the subject of an exemption or approval under section 505 of the FD&C Act. In accordance with section 811(h), if any exemption or approval is in effect under section 505 of the FD&C Act with respect to a substance that falls within the definition of a fentanyl-related substance set forth in this document, such substance is excluded from the temporary scheduling order.

#### *What Is Controlled Under this Temporary Scheduling Order*

On December 29, 2017, as required by 21 U.S.C. 811(h)(A), the DEA Administrator published a notice of intent to issue an order temporarily placing fentanyl-related substances in schedule I. 82 FR 61700. This temporary order places fentanyl-related substances in schedule I of the CSA for two years. DEA may extend the temporary scheduling for an additional year (a total of three years) if proceedings to permanently schedule the substances are pending. As defined in the notice of intent, as

well as in this temporary order, fentanyl-related substances includes any substance not otherwise controlled in any schedule (i.e., not included under any other Administration Controlled Substance Code Number) that is structurally related to fentanyl by one or more of the following modifications:

(A) replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;

(B) substitution in or on the phenethyl group with alkyl, alkenyl, alkoxy, hydroxyl, halo, haloalkyl, amino or nitro groups;

(C) substitution in or on the piperidine ring with alkyl, alkenyl, alkoxy, ester, ether, hydroxyl, halo, haloalkyl, amino or nitro groups;

(D) replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle; and/or

(E) replacement of the *N*-propionyl group by another acyl group.

*How DEA Will Identify Individual Fentanyl-Related Substances That Fall Within This Temporary Scheduling Order*

As indicated, the temporary scheduling order includes all substances that fall within the above definition – even if such substances have not yet emerged on the illicit market in the United States. As a result, DEA cannot currently specify the chemical name of every potential substance that might fall under this new definition. However, because the definition of fentanyl-related substance describes a unique chemical structure, DEA has the authority to under 21 U.S.C. 811(h) to temporarily schedule this category of substance. In the future, if and when DEA identifies a specific new substance that falls

under the definition, the agency will publish in the *Federal Register*, and on the agency website, the chemical name of such substance. Thus, the text of the definition of fentanyl-related substance includes language indicating that it "includes, but is not limited to, the following substances:" It bears emphasis, however, that even in the absence of a future publication by DEA specifically identifying such a substance, the substance is controlled by virtue of this temporary scheduling order if it falls within the definition of fentanyl-related substance.

*Notification to the Secretary of Health and Human Services*

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance in schedule I of the CSA.<sup>5</sup> On November 6, 2017, the Administrator transmitted notice by letter to the Assistant Secretary for Health of HHS of his intent to place fentanyl-related substances, unless listed in another schedule, in schedule I on a temporary basis. The Assistant Secretary responded by letter dated November 29, 2017, and advised that based on a review by the Food and Drug Administration (FDA), they are not aware of any investigational new drug applications or approved new drug applications for fentanyl-related substances as defined above under section 505 of the FD&C Act, 21 U.S.C. 355, and that HHS has no objection to the temporary placement of these substances in schedule I of the CSA. As indicated, in accordance with section 811(h), fentanyl-related substances are defined under this

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<sup>5</sup> As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

temporary scheduling order to exclude any substance for which an exemption or approval is in effect under section 505 of the FD&C Act.

*Grounds for Temporary Scheduling Order*

To find that placing a substance temporarily in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). These factors include, but are not limited to, actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. *Id.* DEA has considered these factors for fentanyl-related substances, as defined above, and finds that the information is consistent across this class of substances. The DEA's three-factor analysis is available in its entirety under "Supporting and Related Material" of the public docket for this action at [www.regulations.gov](http://www.regulations.gov) under Docket Number DEA-476.

Substances that are included in the above-listed structural modifications and any combination of these structural modifications have been found to cause pharmacological effects that are similar to those of fentanyl. It therefore is reasonable to expect that all such substances, even if they have yet to appear on the illicit market in the United States, share the dangerous and potentially lethal properties that have caused the recent spike in fentanyl-related overdose deaths in the United States. While these substances may not yet have appeared in the domestic illicit market, with 21 U.S.C. 811(h), Congress empowered DEA to act proactively to "avoid an imminent hazard to the public safety" by scheduling dangerous substances on a temporary basis before they adversely impact



the public safety. Thus, where, as here, DEA has evidence indicating that certain substances, due to their chemical structure and resulting pharmacological properties, as well as observed patterns of production and trafficking of closely related substances, will pose an imminent hazard to the public safety in the absence of control in schedule I (having considered the relevant factors under 21 U.S.C. 811(h)(3)), DEA may issue a temporary order under 21 U.S.C. 811(h). By temporarily placing these fentanyl-related substances in schedule I, it is DEA's intention to deter the production and introduction of these substances into the United States that traffickers might be considering – before such activity even begins – thereby avoiding an imminent hazard to the public safety. The alternative approach, of only temporarily controlling substances that have already appeared in the illicit U.S. market, is beneficial but has not eliminated the danger these newly created substances pose and is not as effective in preventing future deaths and serious injuries associated with these substances. In addition, by controlling fentanyl-related substances, the temporary scheduling order will facilitate the development of international, national, and local prevention strategies that decrease morbidity and mortality from overdoses caused by or associated with fentanyl-related substances.

For these reasons, DEA has concluded that issuing a temporary scheduling order is necessary to avoid an imminent hazard to the public safety.

#### *Schedule I Classification*

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the

United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

As indicated, DEA finds that the fentanyl-related substances that are temporarily controlled by virtue of this order have a high potential for abuse. Information provided by the Assistant Secretary of HHS indicates that these fentanyl-related substances, as defined, have no currently accepted medical use in treatment in the United States and lack accepted safety for use under medical supervision.

### **Conclusion**

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator issues this temporary scheduling order to place fentanyl-related substances in schedule I of the CSA. Because the Administrator hereby finds that it is necessary to temporarily place fentanyl-related substances in schedule I to avoid an imminent hazard to the public safety, this temporary order scheduling these substances is effective on the date the order is published in the *Federal Register*, and is in effect for a period of two years. DEA may extend the temporary scheduling for an additional year (a total of three years) if proceedings to permanently schedule the substances are pending. 21 U.S.C. 811(h)(1) and (2).

### **Requirements for Handling**

Upon the effective date of this temporary order, fentanyl-related substances will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, fentanyl-related substances must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312, as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Any person who currently handles fentanyl-related substances, and is not registered with the DEA, must submit an application for registration and may not continue to handle fentanyl-related substances as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], unless the DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA on or after [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER] is unlawful and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration to handle fentanyl-related substances must surrender all currently held quantities of fentanyl-related substances.

3. *Security.* Fentanyl-related substances are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of fentanyl-related substances must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of fentanyl-related substances on the effective date of this order must take an inventory of all stocks of these substances on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including fentanyl-related substances) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records.* All DEA registrants must maintain records with respect to fentanyl-related substances pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, 1312, and 1317. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

7. *Reports.* All DEA registrants who manufacture or distribute fentanyl-related substances must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

8. *Order Forms.* All DEA registrants who distribute fentanyl-related substances must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

9. *Importation and Exportation.* All importation and exportation of fentanyl-related substances must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

10. *Quota.* Only DEA registered manufacturers may manufacture fentanyl-related substances in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

11. *Liability.* Any activity involving fentanyl-related substances not authorized by, or in violation of, the CSA, occurring as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

### **Regulatory Matters**

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the *Federal Register* of the intention to issue such order and the grounds upon which such order is to be issued and (2) the date

that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the notice-and-comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this temporary order. In the alternative, even if this order were subject to section 553 of the APA, the Administrator would find that there is good cause to forgo the notice-and-comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be contrary to the public interest in view of the urgent need to control fentanyl-related substances to avoid an imminent hazard to the public safety.

Since this temporary scheduling action is not a “rule” as defined by 5 U.S.C. 601(2), it is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget.

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with

Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act is inapplicable, as it applies only to rules. However, if this were a rule, pursuant to the Congressional Review Act, “any rule for which an agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the federal agency promulgating the rule determines.” 5 U.S.C. 808(2). It is in the public interest to schedule these substances immediately to avoid an imminent hazard to the public safety. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the DEA’s need to move quickly to place these substances in schedule I because they pose an imminent hazard to the public safety, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, this order shall take effect immediately upon its publication. The DEA has submitted a copy of this temporary order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801–808 because, as noted above, this action is an order, not a rule.

**List of Subjects in 21 CFR Part 1308**

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA amends 21 CFR part 1308 as follows:

**PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES**

1. The authority citation for part 1308 continues to read as follows:

**Authority:** 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

2. In § 1308.11, add paragraph (h)(30) to read as follows:

**§ 1308.11 Schedule I.**

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(h) \* \* \*

(30) Fentanyl-related substances, their isomers, esters, ethers, salts and salts of isomers, esters and ethers ..... 9850

(i) Fentanyl-related substance means any substance not otherwise listed under another Administration Controlled Substance Code Number, and for which no exemption or approval is in effect under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355], that is structurally related to fentanyl by one or more of the following modifications:

(A) Replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;

(B) Substitution in or on the phenethyl group with alkyl, alkenyl, alkoxy, hydroxyl, halo, haloalkyl, amino or nitro groups;

(C) Substitution in or on the piperidine ring with alkyl, alkenyl, alkoxy, ester, ether, hydroxyl, halo, haloalkyl, amino or nitro groups;



(D) Replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle; and/or

(E) Replacement of the *N*-propionyl group by another acyl group.

(ii) This definition includes, but is not limited to, the following substances:

(A) [Reserved]

(B) [Reserved]

Dated: February 1, 2018.

**Robert W. Patterson,**

*Acting Administrator.*

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